Premarket Notification [510(k)] Submissions for Electrosurgical Devices for General Surgery

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.
Document issued on: March 24, 2014

You should submit comments and suggestions regarding this draft document within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.regulations.gov. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this document, contact the General Surgery Devices Branch 2, 301-796-6970.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Division of Surgical Devices
General Surgery Devices Branch 2

Preface

Additional Copies

Additional copies are available from the Internet. You may also send an e-mail request to CDRH-Guidance@fda.hhs.gov to receive a copy of the guidance. Please use the document number 1835 to identify the guidance you are requesting.

Table of Contents

Premarket Notification [510(k)] Submissions for Electrosurgical Devices for General Surgery

Draft Guidance for Industry and Food and Drug Administration Staff

This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. Introduction

FDA has developed this guidance document to assist industry in preparing premarket notification submissions [510(k)] for electrosurgical devices intended for use in general surgery. These devices are designed to cut and/or remove tissue and control bleeding through the use of high-frequency electrical current. For the purpose of this guidance, electrosurgical devices may also be called radiofrequency (RF) devices or high frequency (HF) devices.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. Scope

The scope of this document is limited to the Class II, electrosurgical devices and accessories classified under the following regulation number:

> **Section 878.4400 Electrosurgical cutting and coagulation device and accessories.** An electrosurgical cutting and coagulation device and accessories is a device intended to remove tissue and control bleeding by use of high-frequency electrical current.

Electrosurgical devices under this regulation are indicated for general tissue cutting and coagulation. If your device has specific indications, it may require additional information (e.g., clinical data) or may be found to have a new intended use. For more information on this topic, please refer to FDA's "Guidance for Industry: General/Specific Intended Use,"

(http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073945.pdf).

There are electrosurgical devices that have been classified under other medical panels (e.g., 21 CFR 872 for dental). This guidance is not applicable to devices classified under the following regulations:

- Section 872.4920 Dental electrosurgical unit and accessories.
- Section 876.4300 Endoscopic electrosurgical unit and accessories.
- Section 882.4400 Radiofrequency lesion generator.
- Section 882.4725 Radiofrequency lesion probe.
- Section 884.4150 Bipolar endoscopic coagulator-cutter and accessories.
- Section 884.4160 Unipolar endoscopic coagulator-cutter and accessories.
- Section 886.4100 Radiofrequency electrosurgical cautery apparatus.
- Section 886.4115 Thermal cautery unit.

In addition, please be aware that there may be supplemental guidance for electrosurgical devices for other specific indications (e.g., RF vessel sealers). In such instances, supplemental guidance may provide additional recommendations or supersede this guidance. We recommend that you search FDA guidance databases (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm) for any device specific supplemental guidance or contact the General Surgery Devices Branch 2 for more information.

For a new device that combines an electrosurgical device with another device(s) (e.g., mechanical massager or low level light source) into a single system, and is designed to operate simultaneously or in sequence to achieve a desired clinical effect in tissue, additional data requirements are usually necessary to demonstrate the new device is substantially equivalent to the predicate devices working independently. We recommend that you contact the Agency through the pre-submission process to obtain further guidance for data requirements. For information on the pre-submission process see FDA's guidance "Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff" (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm310375.htm).

III. Device Description

We recommend that you identify your device by the applicable regulation number described in Section II and include the following information:

A. Indications for Use

You should provide a clear statement of your device's Indications for Use. The Indications for Use as stated on the Indications for Use Statement page should be identical to that in the 510(k) Summary (if provided in lieu of a 510(k) Statement) and the device labeling. You should also state if the device is a prescription

(including home use) or Over-the-Counter (OTC) device, and indicate this accordingly on the Indications for Use Statement page.

B. Device Design

You should provide a brief description of the device's operating principle(s) and mechanism of action for achieving the intended effects. If the device will be marketed with multiple components or accessories, and the components/accessories are part of the submission, you should provide a list of all components/accessories with accompanying model numbers and/or part numbers. For the purpose of this guidance, components/accessories of electrosurgical devices refer to the electrosurgical unit (ESU), active accessory, neutral electrode, and miscellaneous accessories. If there are components/accessories that have received prior 510(k) clearance or are exempted from the 510(k) requirement, please provide the 510(k) numbers or indicate their exemption status, respectively.

You should provide the following information regarding device design:

1. Device Components

We recommend you provide a brief description of all major components or accessories where applicable to your submission:

- Electrosurgical Unit (may be referred to as an ESU, generator, and/or control console) major functions, performance specifications, and physical specifications
- Active accessory (generally comprised of one or more active electrode(s), active connector or cables, and active handle or hand piece) design, physical specifications, and patient contacting materials
- Neutral electrodes (also commonly called dispersive electrodes, grounding pads, patient return electrodes, or passive/plate electrode) design, physical specifications, and patient contacting materials
- Miscellaneous accessories such as foot pedal, irrigation pumps, suction or smoke evacuation, etc.

2. Submission for Specific Component(s)/Accessories

If your submission is requesting clearance for a specific component or accessory but not the entire electrosurgical device, you should describe the component/accessory. You should discuss how you intend or expect this component/accessory to be used. For example, if the submission is for an active electrode and will only be marketed for use with your own legally marketed devices, you should provide performance testing (see Section XI Performance Data) to demonstrate compatibility with your own legally marketed devices. Also, you should address the likelihood that this active electrode could be used with other manufacturers' electrosurgical devices and, if so, identify the associated risk(s). Whether or not you intend to market the active electrode for use with another manufacturer's device, unless you have incorporated into your device design a way to prevent using your active electrode with other

manufacturers' devices, a risk assessment identifying potential hazards when using your active electrode with other manufacturers' devices should be provided. Based on your risk assessment, you may need to provide additional performance testing to demonstrate this component will be safe and effective when used with other manufacturers' devices.

3. **Photograph and/or Drawing of the Device**
   We recommend you provide high level drawings, diagrams, and/or photographs of the device that can help explain the functions and features. We also recommend you provide a functional block diagram or connection diagram, including all components clearly labeled.

IV. Substantial Equivalence Comparison

We recommend that you compare your device with a legally marketed predicate device(s) that you believe is (are) substantially equivalent to your device with respect to indications for use and technology characteristics per 21 CFR 807.87(f). Side by side comparisons for each major component using a tabular format such as shown in Table 1 are desirable, whenever possible. For each identified difference, please provide further discussion of the difference compared to the predicate and why this difference will not significantly affect safety or effectiveness. You may need to provide performance data to support that even with significant differences the device is as safe and effective as the predicate.

Table 1. Example Comparison Table

Description	Your Device	Predicate Device
Indications for Use		
Prescription or OTC		
Electrosurgical Unit • Major functions (e.g. bipolar, monopolar, temperature sensors, impedance monitor) • Performance Specifications (e.g., output frequency, waveform, power output, voltage output, crest factor) • Physical Specifications		
Active accessory • Monopolar or Bipolar • Physical Dimensions and Design (e.g. size, length, connector type) • Rated voltage • Materials (e.g. electrode, insulation, coating)		

Neutral electrodes • Conductive or Capacitive • Physical Specifications • Materials		
Miscellaneous accessories • Functions • Performance Specifications • Physical Specification • Materials		

When more than one predicate device is identified to establish substantial equivalence of your device, you should provide justification for the use of each predicate. You should address why the combination of features and/or functions into one device does not raise different types of safety and effectiveness questions for each predicate identified. An example of where multiple predicates could be used is if the device includes different technologies that can stand alone separately, but can also be used together for the intended use of cutting and coagulating tissue. If there is a predicate device for each of the technologies, then the combination of these technologies, assuming that the use of one of the functions does not interfere with the others, could be found substantially equivalent. In such an instance, you may need to provide performance data to support your justification.

V. Software

Significance: Software in electrosurgical generators ensures that appropriate energy is delivered to the patient. Adequate software performance testing provides assurance that the device is operating within safe parameters.

Recommendation: Please refer to the FDA guidance "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089593.pdf) for a discussion of the software documentation that you should provide in your submission. The software guidance outlines the type of documentation to be provided based on the "level of concern" associated with the device. FDA generally considers the software for electrosurgical device generators that are intended for general surgery indications to present a "moderate" level of concern. However, new or unusual indications, applications, or technological characteristics may result in a higher level of concern. If you believe that the software in your device presents either a "minor" or a "major" level of concern as defined in the software guidance, you should provide a scientific justification that supports your rationale of the level of concern based on the possible consequences of software failure.

We recommend that you provide a full description of the software/firmware supporting the operation of the subject device following the software guidance, commensurate with the appropriate level of concern. This recommendation applies to original device/systems as well as to any software/firmware changes made to already-marketed devices. Changes to software

must be re-validated and re-verified in accordance with Design Controls, 21 CFR 820.30(g)(i), and documented in the Design History File 21 CFR 820.30(j). Some software changes may warrant the submission of a new 510(k).

If the device includes off-the-shelf software, you should provide the additional information as recommended in the FDA guidance titled "Guidance for Industry, FDA Reviewers and Compliance on Off-the-Shelf Software Use in Medical Devices" (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073778.htm)

As appropriate, you should also provide information on the cybersecurity aspects of your device, including, but not limited to, the following facets of information security with respect to communications features of your device and associated software: confidentiality, integrity, availability and accountability.

Confidentiality assures that no unauthorized users have access to the information.

Integrity is the assurance that the information is correct - that is, it has not been improperly modified.

Availability suggests that the information will be available when needed.

Accountability is the application of identification and authentication to assure that the prescribed access process is being done by an authorized user.

The FDA guidance for industry, "Cybersecurity for Networked Medical Devices Containing Off-The-Shelf (OTS) Software" (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm077823.pdf) provides additional information regarding cybersecurity and medical devices.

Overall, the documentation related to the software contained in the medical device should provide sufficient evidence to describe the role of the software included in the device, and performance testing to demonstrate that the software functions as designed.

VI. Biocompatibility

Significance: Electrosurgical devices contain patient-contacting materials, which, when used as intended, i.e., given the contact type and duration, may induce a harmful biological response.

Recommendation: You should determine the biocompatibility of all patient-contacting materials present in your device. For polymer materials, you should identify each material by trade name and manufacturer. If your materials are identical in composition and processing methods to materials used in a predicate device or another device with the same contact type and duration (e.g., tissue contacting, less than 24 hours) for electrosurgical applications, you may reference previous testing experience in lieu of new testing.

If biocompatibility testing is conducted in accordance with ISO 10993-1 Biological Evaluation of Medical Devices-Part 1: Evaluation and Testing, we recommend that you follow FDA's current guidance on this topic. See Blue Book Memorandum #G95-1 Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing," dated May 1, 1995. FDA is currently in the process of updating the 1995 guidance. For additional information on this topic see FDA's draft guidance "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM348890.pdf). FDA's draft guidance represents FDA's proposed approach on this topic. When final, this document will supersede Blue Book Memorandum #G95-1.

Differences in formulation, processing, sterilization, or device surface properties (e.g., nano structuring) that could affect biocompatibility of the final product may warrant additional biocompatibility testing.

Most active electrodes should be considered external devices that contact tissue/bone/dentin for a limited contact duration (less than 24 hours). As a result, we recommend testing for:

- Cytotoxicity (See ISO 10993-5 Biological evaluation of medical devices – Part 5: Tests for cytotoxicity);
- Intracutaneous reactivity (See ISO 10993-10 Biological evaluation of medical devices – Part 10: Tests for irritation and delayed type sensitivity); and
- Delayed type sensitivity (See ISO 10993-10 Biological evaluation of medical devices – Part 10: Tests for irritation and delayed type sensitivity).

Most dispersive electrodes should be considered external devices that contact only intact skin for a limited contact duration (less than 24 hours). As a result, we recommend testing for:

- Cytotoxicity (See ISO 10993-5 Biological evaluation of medical devices – Part 5: Tests for cytotoxicity);
- Dermal irritation (See ISO 10993-10 Biological evaluation of medical devices – Part 10: Tests for irritation and delayed type sensitivity); and
- Delayed type sensitivity (See ISO 10993-10 Biological evaluation of medical devices – Part 10: Tests for irritation and delayed type sensitivity).

For biocompatibility testing conducted using extraction samples, we recommend that you:

- determine the appropriate amount of test material as outlined in ISO 10993-12 (Biological Evaluation of Medical Devices – Part 12: Sample Preparation and Reference Materials) or an equivalent method, using surface area to extractant volume ratios (mass to extractant volume ratios should only be used if surface area cannot be calculated);
- use both polar and nonpolar extractants;
- describe the condition of the extraction vehicle (e.g., color, presence of any particles);

- explain any changes in the post-extraction vehicle (compared to pre-extraction); and
- describe the details of storage conditions, if applicable.

VII. Sterility

Significance: Electrosurgical devices for general surgery indications come in contact with blood and body tissue and should be adequately sterilized to minimize infections and related complications.

Recommendation: For electrosurgical devices labeled as sterile, we recommend that you provide sterility information for the finished device. For information on sterility information in 510(k) submissions for devices labeled as sterile see FDA's draft guidance "Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile" (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm109884.htm). FDA's draft guidance represents FDA's proposed approach on this topic. You should sterilize the device to a sterility assurance level (SAL) of $1x10^{-6}$ using a sterilization method and cycle that has been validated in accordance with the Quality System Regulation (21 CFR Part 820).

VIII. Reprocessing

Significance: Many of the patient contacting components of electrosurgical devices are reused, and should be adequately cleaned, disinfected and sterilized between uses to minimize infections and prevent device degradation.

Recommendation: Under the FDA labeling regulations (21 CFR Part 801), a device must have adequate directions for use, which include instructions on preparing a device for use. Instructions on how to reprocess a reusable device or a single-use device that is provided non-sterile to the user are critical to ensure that a device is appropriately prepared for its initial and / or subsequent uses. For information on the development and validation of reprocessing instructions in your proposed device labeling, please see FDA's draft guidance "Processing/Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm252999.htm). FDA's draft guidance represents FDA's proposed approach on this topic.

IX. Pyrogenicity

Significance: Pyrogenicity testing is used to help protect patients from the risk of febrile reaction due to gram-negative bacterial endotoxins and/or chemicals that can leach from a medical device (e.g., material-mediated pyrogens).

Recommendation: To address the risks associated with the presence of bacterial endotoxins, electrosurgical devices labeled as "non-pyrogenic" should follow the recommendation in Section VII Sterility. Proposed pyrogen limit specifications have been identified in FDA's draft guidance "Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile" (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm109884.htm). FDA's draft guidance represents FDA's proposed approach on this topic.

To address the risks associated with material-mediated endotoxins, you should follow the recommendations in Section VI Biocompatibility.

For devices intended to be labeled as "non-pyrogenic," we recommend that both the bacterial endotoxin and rabbit material-mediated pyrogen testing be conducted.

X. Shelf Life

Significance: Shelf life testing is conducted to support the proposed expiration date through evaluation of the package integrity for maintaining device sterility and/or evaluation of any changes to device performance or functionality.

Recommendation: With respect to package integrity for maintaining device sterility, you should provide a description of the packaging, including how it will maintain the device's sterility, a description of the package integrity test methods, and a summary of the package integrity test results. FDA recommends that package integrity test methods include simulated distribution and associated package integrity, as well as simulated (and/or real-time) aging and associated seal strength testing, to validate package integrity and shelf life claims. We recommend you follow the methods described in the FDA-recognized series of consensus standards AAMI/ANSI/ISO 11607:2006 "Packaging for Terminally Sterilized Medical Devices."

With respect to evaluating the effects of aging on device performance or functionality, shelf life studies should evaluate the critical physical and mechanical properties of the device that are required to ensure it will perform adequately and consistently during the entire proposed shelf life. To evaluate device functionality, we recommend that you assess each of the bench tests described in Section XI Performance Data and repeat all tests that evaluate design components or characteristics that are potentially affected by aging. For example, aging can affect the performance of most polymer materials used; therefore, tests that evaluate the integrity and performance of the insulation should be repeated after aging. For those bench tests that you do not repeat, you should provide a rationale explaining why the performance characteristics assessed by the tests are not expected to be affected by aging.

We recommend that you provide the protocol(s) used for your shelf life testing and the conclusions drawn from your results. If you use devices subject to accelerated aging for shelf life testing, we recommend that you specify the way in which the devices were aged. For devices or components containing polymeric materials, you should plan to conduct testing on real-time aged samples to confirm that the accelerated aging is reflective of real-time aging. This testing should be conducted in parallel with 510(k) review and clearance, with results documented to file in the design history file (i.e., the test reports do not need to be submitted to FDA).

XI. Performance Data

We recommend that nonclinical testing be performed to demonstrate that each individual component of the device, as well as the electrosurgical device with all the components connected (system), meets all the design specification and performance requirements. In the case where the 510(k) submission is for one or more components of the electrosurgical device but not the entire electrosurgical device (e.g., electrosurgical generator only or active electrodes only), nonclinical testing as a system may still be required using legally marketed components that are most likely to be used with your device. Depending on the substantial equivalence comparison to the predicate(s) above, nonclinical testing may be accomplished with bench testing alone, or may require testing in an *in vivo* or *ex vivo* animal model. The following are recommended nonclinical tests for each major component and for the system.

A. Electrosurgical Unit

For each mode, you should provide a graphical display of the output waveform at the rated load, identifying the associated mode, amplitude, frequency, duty cycle, load used, and crest factor.

For each mode, you should provide a graph displaying the power output at maximum and half of maximum intensity over the range of expected loads (e.g., 100Ω to 2000Ω for monopolar). This information should be derived from experimental test data and not theoretical values and should include a comparison of these curves to the corresponding mode of the predicate device(s).

B. Active Component / Accessory

Mechanical testing of electrosurgical instruments is important to minimize the risks associated with mechanical failure and short circuiting. Although the methods will vary based on the device design, you should assess the potential for damage to the device both before use (e.g., drop tests of the instrument in its packaging) and during use (e.g., bending force). Different considerations will also be necessary for single use instruments versus reusable instruments. For reusable instruments, testing should demonstrate both adequate mechanical strength and electrical performance (e.g., insulation integrity) after multiple reuse and reprocessing cycles. For instruments with actuating parts, we recommend simulated repeated use testing, grasping force,

and force to jaw failure. Testing of cutting performance of surgical scissors should also be performed, where applicable.

C. Neutral Electrodes

Neutral electrode thermal performance, contact impedance, and adhesion testing should be performed in accordance with the currently FDA recognized version of IEC 60601-2-2 Clauses 201.15.101.5, 201.15.101.6 and 201.15.101.7. If alternative test methods and test procedures are developed, a detailed description of the testing and test results should be provided. In addition, you should provide a discussion regarding why the testing and test results are comparable to the currently FDA recognized version of the IEC 60601-2-2 standard.

As these standards may be periodically updated, please check the Recognized Consensus Standards database (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm) for the most current information on which editions are recognized by FDA.

For reusable neutral electrodes, the above testing should be performed following simulated reuse and reprocessing cycles according to the instructions for use.

D. Miscellaneous Components / Accessories

When your electrosurgical device also includes accessories such as a foot pedal, irrigation pump, suction device, or smoke evacuation device, you should provide test results to show that each of those accessories meets all of the design specification and performance requirements.

E. System Testing

In addition to the component testing, testing of the electrosurgical device with all the components and accessories working together as a system may be necessary. The following are examples of system testing that may be needed for electrosurgical devices:

1. **Thermal Effects on Tissue**
   For each mode and active electrode, you should provide a measurement (under magnification) of the size (length, width and depth) of the thermal damage zone, i.e., coagulation necrosis. This testing may be performed on *ex vivo* tissue and should include at least three tissue types (e.g., liver, kidney, muscle tissues) to support a general soft tissue indication. At a minimum, each test should be performed in triplicate at the minimum, default, and maximum intensity settings. We recommend providing the results in a chart and/or graph that indicates the width and depth of thermally damaged zone in relation to the tissue type, intensity setting, and duration of activation.

   For specific tissue type (e.g., lung or colorectal tissue) indications, additional testing may be necessary in a chronic animal study. If you believe a chronic animal study is necessary, we highly recommend that you contact the Agency

through the Pre-Submission process to obtain early feedback on your study design considerations.

2. **Temperature Monitoring**
   For electrosurgical devices that include temperature sensing, you should provide testing to demonstrate that this feature works as intended. Although the methods will vary based on the device design, your testing should demonstrate that the temperature sensing under simulated conditions meets your design specification and performance requirements.

3. **Contact Quality Monitoring (CQM)**
   For electrosurgical generators and dispersive electrodes with contact quality monitoring capabilities, you should provide testing to demonstrate that this feature works as intended. Although the methods will vary based on the contact quality monitoring design, your testing should provide data on conditions where the contact quality monitoring is effective in order to write adequate instructions for use.

4. **Capacitive Coupling**
   For laparoscopic/endoscopic electrosurgical electrodes and accessories, we recommend you test for active coupling resistance between the subject device and a conductive cannula/trocar device under simulated normal use conditions. Please consider the currently FDA recognized version of IEC 60601-2-18 Clause 201.11.101.2(c) for a recommended test set-up and pass/fail criteria.

You should provide complete test reports that include presentation of the test results, the test set-up and method, all test articles/components used, number of samples, predetermined acceptance criteria, study analysis, and a discussion of the results and conclusions drawn from the studies. You should describe the clinical relevance of the acceptance criteria for each test and explain why the test results demonstrate acceptable clinical performance of your device. Non-clinical test conditions should simulate the worst-case conditions that your device is likely to encounter during clinical use. Also, where applicable, the results should be compared to those of your predicate device(s).

XII. Electrical Safety and Electromagnetic Compatibility

Significance: Electromagnetic compatibility (EMC) is the ability of a device to operate properly in its intended use environment without operating unexpectedly due to electromagnetic disturbances or introducing excessive electromagnetic disturbance into that environment.

Recommendation: All electrosurgical devices should undergo basic electrical, thermal, and electromagnetic performance testing to evaluate the potential for insufficient electrical safety and electromagnetic compatibility. We recommend that you conduct the required testing and comply with the labeling requirements outlined in the EN/IEC 60601 standards listed below. As these standards may be periodically updated, please check the Recognized Consensus Standards database for the most current information on which editions are recognized by

FDA. Given the potential variability in the test setup due to different designs and multiple components, sponsors should submit the complete test reports for these standards.

- 60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- 60601-1-2: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
- 60601-2-2: Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories

Additionally, endoscopic/laparoscopic instruments should demonstrate compliance with 60601-2-18: Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment.

According to IEC 60601-2-2, high frequency surgical instruments are intentional emitters of electromagnetic energy and, therefore, testing to IEC 60601-1-2 is only needed for power generators in the idle state (i.e., powered on, but energy not activated). However, even during idle testing, particular attention should be paid to the effects of connected accessories and instruments, such as cord length (for resonant frequency) and instruments that contain electronics. For instruments with different cord lengths, connection types, or electronic components it may not be appropriate to use a single "representative" instrument model for testing purposes.

If your submission is for a specific component of the electrosurgical device, you are still expected to evaluate your component while connected to other components of the electrosurgical device and consistent with how you intend or expect your component will be used.

If your electrosurgical device uses wireless or RFID (radio frequency identification) technology, meeting the IEC 60601 standards is insufficient to demonstrate that your device will not be susceptible to electromagnetic interferences and that your wireless technology will perform reliably. Please review FDA's guidance "Radio-Frequency Wireless Technology in Medical Devices" (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm077210.htm) for a discussion on risks associated with wireless technology and suggestions regarding how to mitigate this risk.

XIII. Clinical Testing

Clinical data are generally not required to support 510(k) submissions for electrosurgical devices that are intended for general surgery indications. However, if your device indications for use or device technology and/or mechanism of action is significantly different when compared to the predicate device(s), and if nonclinical testing is insufficient to establish substantial equivalence, clinical testing may be necessary to establish substantial equivalence

to a predicate device. For example, many electrosurgical devices for aesthetic use have utilized clinical data to demonstrate that the devices are as safe and effective as the predicate.

If you believe that clinical data is necessary or if you are uncertain, we highly recommend that you contact the Agency through the Pre-Submission process to obtain early feedback on study design considerations.

XIV. Labeling

The premarket notification must include labeling in sufficient detail to satisfy the requirements of 21 CFR 807.87(e). Proposed labels, labeling, and advertisements sufficient to describe the electrosurgical device, its intended use, and the directions for use must be provided with a specific intended use statement and any warnings, contraindications, or limitations clearly displayed as described in 21 CFR 807.87(e). Please consider the following suggestions for assistance in preparing labeling that satisfies the requirements of 21 CFR 807.87(e). The following suggestions are aimed at assisting you in preparing acceptable labeling.[1]

As a prescription device, under 21 CFR 801.109, the device is exempt from having adequate directions for lay use. Labeling must, however, include adequate information for practitioner use of the device, including indications, effects, routes, methods, frequency and duration of administration and any relevant hazards, contraindications, side effects and precautions. (21 CFR 801.109(d)).

As stated above in Section XII Electrical Safety and Electromagnetic Compatibility, we recommend that all electrosurgical device submissions demonstrate compliance with the labeling requirements of the EN/IEC 60601 series of standards, including 60601-1, 60601-1-2, 60601-2-2, and (when applicable) 60601-2-18. We also recommend that you include the information below in your labeling.[2]

Electrosurgical systems generally consist of several different interchangeable components used together to create the desired effect, including the ESU, active accessory, neutral electrodes, footswitches, etc. Some of the labeling recommendations below may apply to only a single component or to each component in a system. You should determine which labeling is appropriate, depending on the indications for use, the individual component and how the components may be packaged (together or separately). If your submission is for a specific component, your labeling should describe compatibility requirements and results from your risk assessment.

The list below is not intended to be exhaustive of all the labeling requirements under part 801.

[1] Although final labeling is not required for 510(k) clearance, final labeling must comply with the requirements of 21 CFR 801 before a medical device is introduced into interstate commerce. In addition, final labeling for prescription medical devices must comply with 21 CFR 801.109. Labeling recommendations in this guidance are consistent with the requirements of part 801.

[2] Note that some of the recommended labeling content is already included in the standards, but has been repeated for emphasis. Other recommended content has been modified from the standards.

A. Instructions for Use (User Manual)

1. Indications for Use

Your labeling should clearly state the indications for use of your device as specified in your Indications for Use Statement. This information should be prominently located in the beginning of your directions for use. If your device consists of multiple components with different indications, please specify this in your labeling. If your device is intended for use with another device, we recommend that you identify that device in your labeling.

2. Warnings

We recommend including the following warnings in the instructions for use. Sample language is provided in italics.

a. *DO NOT USE in patients who have electronic implants such as cardiac pacemakers without first consulting a qualified professional (e.g., cardiologist). A possible hazard exists because interference with the action of the electronic implant may occur, or the implant may be damaged.*

b. *DO NOT USE in the presence of flammable anesthetics or oxidizing gases (such as nitrous oxide (N_2O) and oxygen) or in close proximity to volatile solvents (such as ether or alcohol), as explosion may occur.*

c. *DO NOT place instruments near or in contact with flammable materials (such as gauze or surgical drapes). Instruments that are activated or hot from use may cause a fire.*

d. *When not using instruments, place them in a clean, dry, highly visible area not in contact with the patient. Inadvertent contact with the patient may result in burns.*

e. *DO NOT USE with hybrid trocar systems, i.e., a combination of metal and plastic. This may result in alternate site burns due to capacitive coupling. Use only all-metal or all-plastic trocar systems.*

f. *INSPECT instruments and cables for damage prior to each use, especially the insulation of laparoscopic/endoscopic instruments. This may be done visually under magnification or with a high voltage insulation testing device. Insulation failures may result in burns or other injuries to the patient or operator.*

g. *ASPIRATE fluid from the area before activating the instrument. Conductive fluids (e.g., blood or saline) in direct contact with or in close proximity to an active electrode may carry electrical current or heat away from target tissues, which may cause unintended burns to the patient.*

h. *DO NOT activate the instrument when not in contact with target tissue, as this may cause injuries due to capacitive coupling.*

i. *The surface of the active electrode may remain hot enough to cause burns after the RF current is deactivated.*

j. *Due to concerns about the carcinogenic and infectious potential of electrosurgical by-products (such as tissue smoke plume and aerosols), protective eyewear, filtration masks, and effective smoke evacuation equipment should be used in both open and laparoscopic procedures.*

k. *Connect adaptors and accessories to the electrosurgical unit only when the unit is off. Failure to do so may result in an injury or electrical shock to the patient or operating room personnel.*

l. *Prior to increasing the intensity, check the adherence of the neutral electrode and its connections. Apparent low output or failure of the device to function correctly at the normal operating settings may indicate faulty application of the neutral electrode or poor contact in its connections.*

m. If the device is argon enhanced, you should include warnings and recommendations regarding gas embolisms.

n. If the device uses a neutral electrode and does not have a CQM, you should include a warning that loss of safe contact between the neutral electrode and the patient will not result in an alarm.

o. If the device uses a neutral electrode and does have a CQM, you should include a warning that loss of safe contact between the neutral electrode and the patient will not result in an alarm unless a compatible monitoring neutral electrode is used.

3. Cautions

We recommend including the following cautions in the instructions for use. Sample language is provided in italics.

a. *The intensity should be set as low as is necessary to achieve the desired effect.* [unless there is a risk associated with low settings, *e.g.*, argon coagulation]

b. *Keep the active electrodes clean. Build-up of eschar may reduce the instrument's effectiveness. Do not activate the instrument while cleaning. Injury to operating room personnel may result.*

4. Operating Information

Operating instructions should contain detailed information such that the practitioner can set up and use the device safely and for the purposes for which it is intended. In addition, we recommend that you include instructions concerning the proper selection and use of accessories in order to avoid incompatibility and unsafe operation. In particular, you should include advice concerning the compatibility between contact CQMs and neutral electrodes and direct the user to verify that the generator's output voltage does not exceed the rated accessory voltage.

For any accessories that may need to be replaced (e.g., disposable electrodes), you should also provide instructions in your labeling for obtaining replacements (*e.g.*, model number and contact information).

B. Device Labels

In your submission, we recommend that you provide illustrations to show how each component of your device is labeled to demonstrate that all controls, switches and connections (including those for hand switched active electrodes and foot switches) are clearly, concisely and permanently labeled to identify their function and other important information (e.g., Type BF Applied Part). In the submission and the labeling, you should also describe the color of any controls or connections (e.g., blue "coag" button) so that the function of each is apparent. Your labels must include text adjacent to any symbols on your device (or a legend of symbols) that describes their meaning.

C. Package Labels

We recommend that you provide draft package labels, which should include the manufacturer, model number and important information about device reuse, sterility, shelf life, etc. You must include text adjacent to any symbols on your packaging (or a legend of symbols) that describes their meaning.

D. Labeling for Specific Components

1. Electrosurgical Unit

Your directions for use should include information on the output specifications of your device, so that the user can easily understand the energy that is being delivered. We recommend including the following information for each output mode of your device:

a. Graphs or tables illustrating the actual power output (under a specified impedance) for each intensity setting.

b. Graphs displaying the power output at maximum and half-of-maximum intensity over the range of expected impedances.

c. The maximum output voltage and instructions regarding selecting accessories with appropriate voltage ratings.

2. Active components and accessory

Your directions for use should include information on the compatibility of your active electrodes with other components of the electrosurgical device. We recommend including the following information:

a. The rated accessory voltage.

b. The compatible generator model or adequate instructions and criteria for the user to identify an adequate generator.

c. The limitations on generator output settings and duration of activation.

d. A statement referring users to the generator and neutral electrode user manuals for additional instructions.

e. If the instrument is monopolar, clearly communicate to the user that the handpiece is a monopolar device, and that a dispersive electrode should be used with the generator to prevent burns/injury to the patient.

f. If the instrument is reusable, adequate instructions on the cleaning, inspection, and sterilization and how to track the number of uses. You should also include a warning that visual inspection alone may not be sufficient to ensure that the insulation is intact.

g. For ablation of tissue, the labeling should include a recommended ablation time per lesion size, a lesion size and shape range for which the device is effective, directions on how to perform multiple ablations on a single lesion including how you relocate the probe in a lesion, a time versus temperature versus lesion size created chart to inform users of the expected performance, and directions on how the user knows when an ablation is complete.

3. Neutral Electrodes

Your directions for use should include information on the compatibility of your neutral electrodes with other components of the electrosurgical device. We recommend including the following information:

a. The rated accessory voltage.

b. The surface area and size.

c. Adequate instructions for the user to identify a compatible contact quality monitor (CQM) or a warning that it is not compatible with CQMs.

d. The compatible generator model, or adequate instructions and criteria for the user to identify an adequate generator.

e. The limitations on generator output settings and duration of activation.

f. The appropriate patient population (e.g., size, weight).

g. Detailed instructions on how to apply the electrode to the patient, including recommendations for application site selection and preparation, warnings and precautions, and pre-application tests.

4. Components and Accessories

Your directions for use should include information on the compatibility for each of your accessories with the electrosurgical device. For some accessories, such as suction/irrigation pumps and smoke evacuation devices, a separate standalone instructions for use should be considered.

Appendix A: Glossary of Terms

The following terms are defined for the purpose of this guidance only and may or may not correspond to their broader usage.

active accessory – The component of the electrosurgical device used by the operator to produce surgical effects at the intended site on the patient. Generally comprised an active handle, the cord or cable, and the active electrode (monopolar or bipolar).

active electrode – The conductive portion of the electrosurgical device that delivers high density electrical current to the patient at the surgical site. This may or may not be removable from the active handle.

Argon beam coagulator – An electrosurgical device that combines the uses of argon gas with RF current to form a plasma at the surgical site to effect hemostasis in bleeding tissue. Besides Argon gas, other gas (e.g., nitrogen) has been used.

bipolar – An electrosurgical device in which the current flows between two active electrodes placed in close proximity.

coagulation – The change of a liquid, especially blood, to a solid. This is considered separate from coagulation necrosis.

coagulation necrosis – Necrosis in which the affected cells or tissue are converted into a dry, opaque, fairly homogenous eosinophilic mass as a result of the coagulation of protein.

contact quality monitor (CQM) – A component of a monopolar electrosurgical system that monitors the contact between the neutral electrode and the patient. The CQM produces an alarm if the contact becomes insufficient and the patient is at risk for burns.

continuity monitor – A component of a monopolar electrosurgical system that monitors the connection between the neutral electrode and the generator. The continuity monitor produces an alarm if the connection is lost, but it cannot detect if there may be a high current density through the neutral electrode.

dispersive electrode – An electrode connected to the patient, in an anatomical location away from the surgical site, to provide a return path for the high frequency current. The dispersive electrode has a large area relative to the active electrode in order to provide a low current density. Also known as: patient plate, ground pad, return electrode, neutral electrode, inactive electrode, passive electrode, indifferent electrode, etc.

electrocautery – The use of electric current to heat an instrument, which is applied to tissue to create an effect. The current passes through the instrument only and not through the patient's tissue.
NOTE: The term electrocautery is often used incorrectly to refer to electrosurgical devices. To prevent confusion, FDA recommends that you avoid misuse of this term.

electrosurgical device – A device that passes high-frequency electrical current through soft tissues for the purpose of removing tissue or controlling bleeding.

ESU – acronym for electrosurgical unit – This term may be used to refer to the generator only or to the entire system (generator plus electrodes and accessories). It may also be used as a descriptive term for an electrode or accessory (e.g., "ESU handpiece").

generator – The component of the electrosurgical system that produces the high frequency current waveform that is delivered to tissues via the connecting cable(s), instrument(s), and electrode(s).

hyfrecator – A type of monopolar electrosurgical device in which the current flows from a single active electrode at the surgical site and returns to earth (ground) through the patient's own body capacitance.

instrument – The component of the electrosurgical system that is manipulated by the operator and applied to the surgical site, generally consisting of the handle and active electrode.

monopolar – An electrosurgical technique in which the current flows from a single active electrode at the surgical site, through the patient, to a relatively distant neutral electrode.

radiofrequency (RF) – Generally refers to frequencies ranging from 100 kHz to 5 MHz. This is intended to exclude other frequencies (e.g., microwave ablation devices) that may technically fall within the radiofrequency portion of the electromagnetic spectrum but operate in a fundamentally different manner.

vessel sealer– An electrosurgical device intended to seal isolated blood and lymphatic vessels for hemostasis, as an alternative to ties. Usually bipolar.